

Stemetil[®]

(s-tem-e-til)

Prochlorperazine (pro-klor-per-a-zeen)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Stemetil.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Stemetil against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Stemetil is used for

Stemetil belongs to a group of medicines called phenothiazines. It helps to correct chemical imbalances in the brain, allowing it to function correctly. These chemicals may also affect the parts of the brain which control nausea (feeling sick) and vomiting.

Stemetil is used to treat nausea, vomiting and dizziness due to various causes, including migraine (severe headache).

Your doctor may have prescribed Stemetil for another reason.

Ask your doctor if you have any questions about why Stemetil has been prescribed for you.

This medicine is available only with a doctor's prescription.

Stemetil is not recommended for use in children (under the age of 2 years or children under 10kg in weight).

Before you take it

When you must not take it

Do not take Stemetil if you have an allergy to:

- Stemetil
- the group of medicines called phenothiazines
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to Stemetil may include:

- shortness of breath, wheezing or difficulty in breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

You should not take Stemetil if you have any of the following medical conditions:

- shock
- disease of the blood with a low number of blood cells
- yellowing of the skin and/or eye, also called jaundice

Stemetil must not be given to anyone who is unconscious or in a coma.

Do not take any medicines that cause drowsiness while you are taking Stemetil.

Do not use Stemetil suppositories if you are younger than 16 years old.

Do not take Stemetil after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take Stemetil if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking Stemetil, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant.

Like most phenothiazine medicines, Stemetil is not recommended for use during pregnancy. If there is a need to take Stemetil during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

Tell your doctor or pharmacist if you are breastfeeding or plan to breastfeed.

It is recommended that you do not breastfeed while taking Stemetil, as it is not known whether Stemetil passes into breast milk.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- phaeochromocytoma, a rare tumour of the adrenal glands which sit near the kidneys.
- Parkinson's disease, a disease of the brain affecting movement which causes trembling, rigid posture, slow movement and a shuffling, unbalanced walk.
- myasthenia gravis, a disease of the muscles causing drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms or legs
- kidney problems
- heart and blood vessel problems, low blood pressure
- blood clots
- liver disease
- prostate problems
- bowel problems
- epilepsy, seizures or fits
- low blood calcium levels
- decreased thyroid activity
- glaucoma, a condition in which there is usually a build-up of fluid in the eye
- neuroleptic malignant syndrome, a reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.
- a reaction to some medicines with uncontrollable twitching or jerking movements of the arms and legs.
- dementia
- diabetes
- schizophrenia

- depression

Tell your doctor if you are about to have any surgery which requires a general anaesthetic.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Stemetil.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Stemetil may interfere with each other. These include:

- some medicines used to control depression or mood swings
- medicines metabolised by CYP2D6 enzymes such as amitriptyline
- alcohol
- desferrioxamine, a drug used in iron overdose
- procarbazine, an anticancer drug
- some medicines used to control epilepsy
- medicines used to treat Parkinson's disease
- anticholinergic medicines which are used to relieve stomach cramps, spasms and travel sickness
- atropine, a medicine which may be used in some eye drops or cough and cold preparations
- some oral medicines used to prevent your blood from clotting
- medicines used to treat high blood pressure and fluid build-up in your body
- medicines used to treat a fast or irregular heart beat e.g. amiodarone, quinidine, disopyramide.
- medicines that can slow your heart beat e.g. diltiazem, verapamil.

- medicines that can reduce potassium levels in the blood e.g. diuretics, laxatives.
- other medicines that can affect your heart rate e.g. methadone, pentamidine.

These medicines may be affected by Stemetil or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Stemetil.

How to take it

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how much Stemetil you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

Adults' dose:

The usual recommended dose for nausea and vomiting is 1 or 2 tablets two to three times daily. If you are not able to take a tablet, then one 25mg suppository or a 1mL (12.5mg) injection is the recommended dose.

The usual recommended dose for dizziness is 1 or 2 tablets three to four times daily.

Children's dose:

The recommended dose for nausea, vomiting and dizziness is 1 tablet two to three times a day.

How to take it

Tablets:

Swallow Stemetil tablets whole with a full glass of water. Do not chew the tablets.

Suppository:

1. Stemetil may be given as a suppository. First wash your hands well with soap and water, then follow these instructions: Go to the toilet and empty your bowels if possible. Do not strain.
2. Feel the suppository through its plastic shell. If it feels very soft, chill it in the fridge or cool it by holding it under cold water for several minutes
3. Remove the suppository from its shell
4. Moisten the suppository by dipping it briefly in cool water
5. Put one foot up on the side of the bath or toilet, raising the knee to the chest
6. Insert the suppository, pointed end first, gently into the rectum (back passage)
7. Try not to go to the toilet for at least one hour to allow the suppository to work.

Injection:

Stemetil may be given as an injection into a muscle. Stemetil injection should only be given by a doctor, nurse or other trained person.

When to take it

It does not matter if you take Stemetil before or after food.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

How long to take it

Continue taking Stemetil for as long as your doctor tells you.

If you take too much (overdose)

Do not try to vomit.

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 POISON, 0800 764 766 in New Zealand) or go to Accident and Emergency at your nearest hospital if you think that you, or anyone else, has taken too much Stemetil. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdose may include the following:

- coma
- restlessness, shaking, muscle twitching, muscle weakness, spasm
- confusion
- excitement or agitation
- low blood pressure
- fast heart beat
- decrease in body temperature
- small pupils in the eye
- difficulty in swallowing or breathing
- blue skin

Your doctor or pharmacist has information on how to recognise and treat an overdose. Ask your doctor or pharmacist if you have any concerns.

While you are taking it

Things you must do

Tell your doctor immediately if you notice any uncontrolled movements of the tongue, face, mouth or jaw, such as puffing of the cheeks, puckering of the mouth or chewing movements.

These are symptoms of a very rare condition called tardive dyskinesia,

which may develop in people taking phenothiazine medicines, including Stemetil.

The condition is more likely to occur during long term treatment with Stemetil, especially in elderly women. In very rare cases, this may be permanent.

Avoid exposure to direct sunlight.

Stemetil may cause you to become sensitive to sunlight.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking Stemetil.

If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking Stemetil.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Stemetil.

If you become pregnant while taking Stemetil, tell your doctor immediately.

Things you must not do

Do not give Stemetil to anyone else, even if they have the same condition as you.

Do not take Stemetil to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking Stemetil, or lower the dosage, even if you are feeling better, without checking with your doctor.

If you stop taking Stemetil suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase. To prevent this, your doctor may gradually reduce the amount of Stemetil you take each day before stopping completely.

Things to be careful of

Be careful driving or operating machinery until you know how Stemetil affects you.

As with other medicines, Stemetil may cause dizziness, light-

headedness, tiredness, drowsiness in some people.

Make sure you know how you react to Stemetil before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

If you drink alcohol, dizziness or light-headedness may be worse.

If Stemetil makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position. Getting up slowly may help.

Be careful when drinking alcohol while taking Stemetil. Combining Stemetil and alcohol can make you more sleepy, dizzy or light-headed.

Your doctor may suggest you avoid alcohol while you are being treated with Stemetil.

If outdoors, wear protective clothing and use at least a 15+ sunscreen.

Stemetil may cause your skin to be much more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness, or severe sunburn. If your skin does appear to be burning, tell your doctor.

Make sure you keep cool in hot weather and keep warm in cool weather.

Stemetil may affect the way your body reacts to temperature changes.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Stemetil.

Stemetil helps most people with nausea, vomiting and dizziness, but it may have unwanted side effects in a few people.

All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need

medical treatment if you get some of the side effects. If you are over 65 years of age you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

If you get any side effects, do not stop taking Stemetil without first talking to your doctor or pharmacist.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- constipation
- dry mouth
- drowsiness
- restlessness
- trembling, rigid posture, mask-like face, slow movements and a shuffling unbalanced walk
- twitching
- blurred vision

The following side effects are less common:

- low blood pressure
- changes in heart beats
- swelling of the hands, ankles or feet
- skin rash
- for females: unusual secretion of breast milk, irregular periods
- for males: breast enlargement, difficulty in ejaculating
- severe pain in the stomach with bloating, cramps and vomiting
- difficulty passing urine
- yellowing of the skin and/or eyes
- headache
- insomnia
- seizures
- dizziness
- agitation
- Brownish spots in the eye
- difficulty in breathing

If any of the following happen, tell your doctor or pharmacist immediately or go to Accident and Emergency at your nearest hospital:

- Unusual muscle tone or spasms causing distortion of the body in children
- shortness of breath, wheezing or difficulty in breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

These are very serious side effects.

You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using Stemetil

Storage

Stemetil ampoules for injection should be stored at a pharmacy or hospital. The injection should be kept below 25°C and protected from light.

Keep Stemetil suppositories in a cool dry place where the temperature stays below 25°C. Protect from light.

Keep Stemetil tablets in a cool dry place where the temperature stays below 30°C. Protect from light.

Keep your Stemetil in the pack until it is time to take them.

If you take the tablets or suppositories out of the pack, they may not keep well.

Do not store Stemetil or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking Stemetil, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Product Description

What it looks like

Stemetil tablets* are white, round and marked with "S". Tablets are available in packs of 25.

Stemetil suppositories* are cream, smooth, torpedo shaped and are available in packs of 5.

Stemetil for injection is a clear liquid in a 1mL glass ampoule, in a pack of 10 ampoules.

Ingredients

Stemetil tablets* contain:

prochlorperazine maleate 5mg (active ingredient), wheat starch, calcium hydrogen phosphate dihydrate, magnesium stearate, sodium lauryl sulfate.

Stemetil suppositories* contain:

- prochlorperazine base equivalent to 25mg prochlorperazine maleate (active ingredient)
- suppository base (saturated vegetable fat).

Stemetil ampoules contain:

- prochlorperazine mesilate 12.5 mg/mL (active ingredient)
- sodium chloride
- sodium sulfite

- sodium metabisulfite
- monoethanolamine
- water for injection.

Manufacturer/Sponsor

Stemetil is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Stemetil is supplied in New Zealand by:

sanofi-aventis new zealand limited

Level 8,

56 Cawley Street

Ellerslie

Auckland

Registration Numbers:

Stemetil tablets

AUST R 27564

Stemetil suppositories

25mg - AUST R 27557

Stemetil ampoules for injection

AUST R 27555

Date of preparation:

September 2018

* Stemetil tablets and suppositories currently not available in New Zealand

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